SPINAL LIGAMENT MODIFICATION DEVICES

TECHNICAL FIELD OF THE INVENTION

The present invention relates to a minimally invasive method, device and system for treating spinal disorders using imaging guidance. This invention also relates to devices used to reduce stenosis and increase the cross-sectional area of the spinal canal and to devices used to treat excess fat within the spinal canal or epidural lipomatosis. This invention also relates to methods, devices, therapies and medications used to treat disorders that involve the epidural space.

BACKGROUND OF THE INVENTION

The spine comprises a stack of vertebrae with an intervertebral disc between adjacent vertebrae. As shown in Figure 1, each vertebra 10 includes a vertebral body 12 that supports a bony ring 14. The bony ring 14 consists of laminae 16, spinous process 18, transverse processes 20, superior articular processes 22, and pedicles 24. Together with vertebral body 12, these vertebral components define the spinal canal. The laminae 16 are joined in the midline by the spinous process 18. In the cervical and thoracic region the dural sac 32 contains the spinal cord, which comprises nerves 34 surrounded by cerebrospinal fluid. The fluid-filled sac is therefore compressible. The ligamentum flavum 26 is an elastic yellow ligament connecting the laminae of adjacent vertebrae.

In degenerative conditions of the spine, narrowing of the spinal canal (stenosis) can occur. Lumbar spinal stenosis is often defined as a dural sac cross-sectional area less than 100 mm_2 or an anteroposterior (AP) dimension of the canal of less than 10-12 mm for an average male.

The source of most cases of lumbar spinal stenosis is thickening of the ligamentum flavum. Spinal stenosis may also be caused by subluxation, facet joint hypertrophy, osteophyte formation, underdevelopment of spinal canal, spondylosis deformans, degenerative intervertebral discs, degenerative spondylolisthesis, degenerative arthritis, ossification of the vertebral accessory ligaments and the like. A less common cause of spinal stenosis, which usually affects patients with morbid obesity or patients on oral corticosteroids, is excess fat in the epidural space. The excessive epidural fat compresses the dural sac, nerve roots and blood vessels contained therein and resulting in back and leg pain and weakness and numbness of the legs. Spinal stenosis may also affect the cervical and, less commonly, the thoracic spine.

Patients suffering from spinal stenosis are typically first treated with exercise therapy, analgesics and anti-inflammatory medications. These conservative treatment options frequently fail. If symptoms are severe, surgery is required to decompress the canal and nerve roots.

To correct stenosis in the lumbar region, an incision is made in the back and the muscles and supporting structures are stripped away from the spine, exposing the posterior aspect of the vertebral column. The thickened ligamentum flavum is then exposed by removal of the bony arch (lamina) covering the back of the spinal canal (laminectomy). The thickened ligament can then be excised with sharp dissection with a scalpel or punching instruments such as a Kerison punch that is used to remove small chips of tissue. The procedure is performed under general anesthesia. Patients are usually admitted to the hospital for approximately five to seven days depending on the age and overall condition of the patient. Patients usually require between six weeks and three months to recover from the procedure. Many patients need extended therapy at a rehabilitation facility to regain enough mobility to live independently.

Much of the pain and disability after an open laminectomy is due to the tearing and cutting of the back muscles, blood vessels and supporting ligaments and nerves that occurs during the exposure of the spinal column. Also, because these spine stabilizing back muscles and ligaments are stripped and cut off, the spine these patients frequently develop spinal instability post-operatively.

Minimally invasive techniques result in less post-operative pain and faster recovery compared to traditional open surgery. Percutaneous interventional spinal procedures can be performed with local anesthesia, thereby sparing the patient the risks and recovery time required with general anesthesia. Another advantage is that there is less damage to the paraspinal muscles and ligaments with minimally invasive techniques reducing pain and preserving these important stabilizing structures.

Various techniques for minimally invasive treatment of the spine are known. Microdiscectomy is performed by making a small incision in the skin and deep tissues to create a portal to the spine. A microscope is then used to aid in the dissection of the adjacent structures prior to discectomy. The recovery for this procedure is much shorter than traditional open discectomies. Percutaneous discectomy devices with fluoroscopic guidance have been used successfully to treat disorders of the disc but not to treat spinal stenosis or the ligamentum flavum directly. Arthroscopy or direct visualization of the spinal structures using a catheter or optical system have also been proposed to treat disorders of the spine including spinal stenosis however these devices still use miniaturized standard surgical instruments and direct visualization of the spine similar to open surgical procedures. These devices and techniques are limited by the small size of the canal and these operations are difficult to perform and master. Also these procedures are painful and often require general anesthesia. The arthroscopy procedures are time consuming and the fiber optic systems are expensive to purchase and maintain.

In addition, because the nerves of the spine pass through the core of the spine directly in front of the ligamentum flavum, any surgery, regardless of whether is open or percutaneous includes a risk of damage to those nerves.

Hence, it remains desirable to provide a simple method and device for treating spinal stenosis and other spinal disorders without requiring open surgery. It is further desired to provide a system whereby the risk of damage to the thecal sac containing the spinal nerves can be reduced.

SUMMARY OF THE INVENTION

The present invention provides a method, device and system for treating spinal stenosis or other spinal disorders using image guidance in combination with percutaneous techniques. The present system is referred to as a minimally invasive ligament decompression (MILD) device. In some embodiments, the present invention provides a means for compressing the thecal sac within the epidural space so as to provide a safety zone in which further surgical procedures may be performed without risk of damaging nearby tissues or the thecal sac itself.

In further embodiments, the present method comprises the steps of a) percutaneously accessing the epidural space in a region of interest with image guidance; b) at least partially compressing the thecal sac in the region of interest by injecting a fluid into the epidural space to form a safety zone; c) percutaneously accessing a working zone in at least one of the ligamentum flavum and overlying dorsal tissues with image guidance, where the safety zone lies between the working zone and thecal sac; d) inserting a tissue removal tool into the working zone; e) using the tool remove tissue so as to reduce the stenosis; and f) utilizing at least one imaging system to identify tissues for removal. By way of example, radiologic imaging may be used to safely guide the tool(s) to target tissues and visualize the position of the tool during at least part of the process.

In preferred embodiments, the device provides an anchored pathway to the working zone so that excised tissue can be shuttled out of the area for successive extractions without time consuming repositioning of the tool(s). In other embodiments, the tool can be repositioned as often as is necessary to achieve the desired modifications. In still other embodiments, the present invention includes percutaneous methods for placing a retractable anchor in the ligamentum flavum and attaching it to the fascia or bone so as to retract the ligamentum flavum, thus expanding the spinal canal. In still other embodiments, the invention includes a percutaneous mechanical suture system and method for placing a stitch in the ligament and then anchoring the stitch so as to retract the ligamentum flavum. The laminotomy site can serve as a site for a bone anchor and/or flange for a suture to anchor the ligament.

Particular embodiments of the invention include a method for treating stenosis in a spine, the spine including a thecal sac and a canal and an epidural space therebetween, wherein the

stenosis determines a region of interest in the spine. The method may comprise the steps of a) percutaneously accessing the epidural space in the region of interest, b) compressing the thecal sac in the region of interest by injecting a fluid to form a safety zone and establish a working zone, with the safety zone lying between the working zone and the thecal sac, c) inserting a tissue removal tool into tissue in the working zone, d) using the tool to percutaneously reduce the stenosis. It is preferred to use at least one imaging system to visualize the position of the tool during at least a part of step d).

Step d) may include 1) engaging adjacent tissue in the working zone, 2) excising the engaged tissue, 3) removing the resulting tissue section from the working zone, and 4) repeating steps 1) through 3) until a desired amount of tissue has been removed. The removed tissue may comprise a portion of the ligamentum flavum, fat, and/or bone. Alternatively, the step d) may include i) providing an anchor having first and second tissue-engaging ends, ii) engaging the ligamentum flavum with the first tissue-engaging end, iii) using the engaged first end to pull at least a portion of the ligamentum flavum into a desired position, and iv) using the second tissue-engaging end to anchor the anchor such that the ligamentum flavum is retained in a desired position. The anchor may be anchored to paraspinous tissue or to other bone.

The invention also relates to an injectable fluid, which may include a contrast agent and may have a temperature-dependent viscosity such that it is more viscous at 37°C than at 30°C.

The tool of steps c) and d) may include an outer cannulated scalpel or needle, a tissue-engaging means, and a cutting or resecting element and may further include means for removing tissue from the tissue-engaging means. The tissue-engaging means may comprise a resilient hook.

Some embodiments of the invention may take the form of a kit for performing a procedure on a spine, in which the kit includes an insertion member for accessing the epidural space, and an expandable device adapted to be inserted into the epidural space by the insertion member and expanded so as to compress a portion of the thecal sac and provide a safety zone within the epidural space. The expandable device may comprise a volume of a contrast medium, such as a radio-opaque non-ionic myelographic contrast medium, and/or may comprise a volume of a medium that is injectable at ambient temperatures and more viscous at body temperature. The contrast medium may include a bioactive agent and/or a steroid.

The kit may further include a surgical device, which in turn may comprise a hollow cannulated scalpel or outer needle having a side aperture proximal its distal end, and an elongate body housed within the outer needle and comprising two radially extendable arms constructed such that radially extending the arms causes them to extend outward through the side aperture and retracting said arms causes them to close. In other embodiments, the kit may comprise means for

engaging the ligamentum flavum and means for resecting a section of the ligamentum flavum and the means for resecting may in turn comprise a trocar, a barbed member coaxially received within the trocar, and a blade. In other embodiments, the surgical device may comprise means for engaging a first anatomical structure and means for affixing the first anatomical structure to a second anatomical structure. Alternatively, the surgical device may comprise means for engaging the ligamentum flavum and soft tissues in the Para spinal region of the patient so as to anchor the ligamentum flavum, and/or means for engaging and retracting the ligamentum flavum and means for anchoring the retracted ligamentum flavum.

In still other embodiments, a percutaneous tool for treating a stenosed spine by removing tissue therefrom, comprises an cannulated scalpel, a first tissue-engaging means housed within the cannulated scalpel, and a cutting element configured to resect a sample of tissue that is engaged by the first tissue-engaging means. The cannulated scalpel may include a side aperture through which the first tissue-engaging means engages the tissue and the tool may further include a second tissue-engaging device that is adapted to remove the resected tissue sample from the first tissue-engaging device. The second tissue-engaging device may comprise a keyhole slot.

In still other embodiments, a device for removing tissue from a stenosed spine may comprise a hollow outer needle having a side aperture proximal its distal end, an elongate body housed within the outer needle and comprising two radially extendable arms constructed such that radially extending the arms causes them to extend outward through said side aperture and retracting the arms causes them to close. Each arm may include an opposing edge and at least one opposing edge may include teeth or ridges or the opposing edges may comprise cutting blades.

In certain embodiments, the present percutaneous tissue excision system may include an inner needle having one or more barbs extending around 120 degrees of its circumference. The barb(s) may be directed toward the proximal end of the needle. The tool may further include an occluding member that closes a side aperture in the cannula may include a distal cutting edge adapted to cut tissue. The tool may further comprise an outer cutting member. The tissue-engaging components of the device preferably comprise a resilient metal that can withstand repeated elastic deflections.

In yet further other embodiments, a method for preventing leakage of cerebrospinal fluid from an opening in a thecal sac in a spine may comprise accessing the epidural space in the vicinity of the opening and inserting a volume of fluid into the epidural space, where the fluid thickens as it attains body temperature such that the fluid blocks the opening in the thecal sac.

In further embodiments, a bone cutting device can be used to access the ligamentum flavum and epidural space, to perform a laminotomy or to allow placement of a cannula. Using a

cannula fixed within (extending through) the lamina, a cutting device can be inserted into and removed from the ligamentum flavum and/or epidural space. Real-time use of fluoroscopy or other imaging means during the subsequent MILD procedure can be minimized with the appropriate placement of tools following use of the bone cutting device. The laminotomy creates a portal and gives a steady purchase for instruments and instrument exchange. In addition, either the laminotomy site or the neighboring tissue, including bone and/or other tissue, can be used as an anchoring site for sutures or other tissue-engaging means.

BRIEF DESCRIPTION OF THE DRAWINGS

For a more complete understanding of the invention, reference is made to the accompanying drawings, wherein:

Figure 1 is an illustration of a vertebra showing the spinal canal with the thecal sac and a normal (un-stenosed) ligamentum flavum therein;

Figure 2 is an illustration of a vertebra showing the spinal canal with the thecal sac and a thickened ligamentum flavum therein;

Figure 3 is an enlarged cross-section of the spine of Figure 2, showing a safety zone created by compression of the thecal sac;

Figure 4 is the enlarged cross-section of Figure 3, showing a tissue removal tool positioned in the ligamentum flavum;

Figures 5-9 are a series of illustrations showing tissue excision by a tissue-excision tool constructed in accordance with a first embodiment of the invention;

Figures 10-14 are a series of illustrations showing tissue excision by a tissue-excision tool constructed in accordance with a second embodiment of the invention;

Figures 15 and 17 are sequential illustrations showing removal of tissue from a tissue-excision tool by a tissue-removal device constructed in accordance with an embodiment of the invention;

Figures 16 and 18 are end views of the tissue-removal device of Figures 15 and 17, respectively;

Figure 19 shows an alternative embodiment of a grasping needle with a corkscrew shape;

Figure 20 is a perspective view of a tissue-excision tool constructed in accordance with a third embodiment of the invention;

Figures 21 and 22 are enlarged cross-sectional and perspective views, respectively, of the grasping device of Figure 20 in its retracted position;

Figures 23 and 24 are enlarged cross-sectional and perspective views, respectively, of the grasping device of Figure 20 in its extended position;

Figure 25 is a schematic illustration of one embodiment of a double-ended ligament anchor being deployed in a ligamentum flavum;

Figure 26 shows the device of Figure 25 after full deployment;

Figures 27 is a perspective view of an entire tool constructed in accordance with preferred embodiments;

Figure 28 is an enlarged cross-sectional view of the distal tip of the tool of Figure 27 with the aperture partially opened;

Figure 29 is a cross-sectional view of the handle end of the tool of Figure 27;

Figure 30 is cross-section of a tissue-removal device constructed in accordance with an alternative embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The epidural space is the space between the ligamentum flavum and the thecal sac. This space is filled with blood vessels and fat. The nerves contained within the thecal sac are normally surrounded by cerebrospinal fluid (CSF). When the ligamentum flavum hypertrophies, the blood vessels that supply the nerves of the cauda equina are compressed. This results in ischemic pain termed spinal claudication. The nerve roots may also be compressed resulting in back and/or leg pain.

Referring again to Figure 1, the posterior border of the normal epidural space 30 is formed by the normally thin ligamentum flavum 26 and posterior epidural fat (not shown). Ligamentum flavum 26 extends from the lamina above the interspinous space to the lamina below the interspinous space. The dural sleeve (thecal sac) 32 contains nerve roots 34 surrounded by cerebrospinal fluid. The nerve roots 34 normally comprise only a small proportion of the thecal sac volume.

In Figure 2, spinal stenosis is present. Ligamentum flavum 26 is markedly thickened, compressing the posterior margin of dural sleeve 32. As shown in Figure 2, the posterior margin of the dural sleeve 32 is apposed to the ligamentum flavum and the epidural space is only a potential space. Because more than 90 % of the volume of the thecal sac in the lumbar region is filled by CSF, the thecal sac is highly compressible. Thus, even though stenosis may be causing compression of the thecal sac (and associated pain or discomfort), in most instances it will be possible to temporarily compress the thecal sac further. Thus, according to preferred embodiments of the invention, thecal sac 32 is compressed in a region of interest by applying pressure to the outside of the sac so that at least a portion of the CSF is forced out of the region of interest.

Creation of Safety Zone

According to certain embodiments, thecal sac 32 is compressed by injecting a standard radio-opaque non-ionic myelographic contrast medium or other imagable or non-imagable medium into the epidural space in the region of interest. This is preferably accomplished with a percutaneous injection. The result is illustrated in Figure 3. The presence of the fluid gently compresses and displaces the dural sleeve 32 in the region of interest, creating a safety zone 40 between thecal sac 32 and ligamentum flavum 26. Sufficient injectable fluid is preferably injected to displace the CSF out of the region of interest and compress the thecal sac to at least a desired degree. The injected medium is preferably substantially contained within the confines of the epidural space extending to the margins of the nerve root sleeves. The epidural space is substantially watertight and the fatty tissues and vascularization in the epidural space, combined with the viscous properties of the preferred fluids, serve to substantially maintain the injected medium in the desired region of interest. This novel method for protecting the neural column may be referred to hereinafter as "contrast-guided dural protection."

Once a safety zone 40 has been created, a tool 100, such as the tissue excision devices and tissue retraction devices described below, can be inserted into the ligamentum flavum 26, as illustrated in Figure 4. While it is preferred that the tip of the tool remain within the ligament as shown, the presence of safety zone 40 ensures that the thecal sac will not be damaged even if the tool breaks through the anterior surface of ligament 26. For insertion of the tool, a fluoroscopic window of access (FWA) is defined by the inferior margin of the lamina (contra lateral to the point of instrument entry in the soft tissues) and the dorsal margin of the contrast material that defines the epidural space. This FWA is roughly orthogonal to the long axis of the cutting instrument, which parallels the inferior surface of the lamina as in Figure 4. The fluoroscopic plane of projection is preferably but not necessarily oriented 20-45 degrees from normal (AP projection).

Because the present techniques are preferably performed percutaneously, certain aspects of the present invention can be facilitated by imaging. In this context, the spine can be imaged using any suitable technology, including but not limited to 2D, 3D fluoroscopy, CT, MRI, ultrasound or with direct visualization with fiber optic or microsurgical techniques. Stereotactic or computerized image fusion techniques are also suitable. Fluoroscopy is currently particularly well-suited to the techniques disclosed herein. Fluoroscopic equipment is safe and easy to use, readily available in most medical facilities, relatively inexpensive. In a typical procedure, using direct biplane fluoroscopic guidance and local anesthesia, the epidural space is accessed adjacent to the surgical site as described above.

If the injected medium is radio-opaque, as are for example myelographic contrast media, the margins of the expanded epidural space will be readily visible using fluoroscopy or CT

imaging. Thus, the safety zone created by the present contrast-guided dural compression techniques can reduce the risk of damage to the spinal cord during procedures to remove or displace portions of the ligamentum flavum and/or laminae in order to treat spinal stenosis.

Injectable Medium

If desired, the injected medium can be provided as a re-absorbable water-soluble gel, so as to better localize the safety zone at the site of surgery and reduce leakage of this protective layer from the spinal canal. An injectable gel is a significant improvement on prior epidural injection techniques. The gel is preferably substantially more viscid than conventional contrast media and the relatively viscid and/or viscous gel preferably tends to remain localized at the desired site of treatment as it does not spread as much as standard liquid contrast media that are used in epidurography. The injected gel is preferably sufficiently viscous that it remains substantially within the local epidural space. This results in more uniform compression on the thecal sac and less leakage of contrast out of the canal. In addition, preferred embodiments of the gel are re-absorbed more slowly than conventional contrast media, allowing for better visualization during the course of the surgical procedure.

In some embodiments, a contrast agent can be included in the gel itself, so that the entire gel mass is imagable. In other embodiments, an amount of contrast can be injected first, followed by the desired amount of gel, or an amount of gel can be injected first, followed by the desired amount of contrast. In this case, the contrast agent is captured on the surface of the expanding gel mass, so that the periphery of the mass is imagable.

Any standard hydrophilic-lipophilic block copolymer (Pluronic) gel such as are known in the art would be suitable and other gels may be used as the injectable medium. The gel preferably has an inert base. In certain embodiments, the gel material is liquid at ambient temperatures and can be injected through a small bore (such as a 27 gauge needle). The gel then preferably becomes viscous when warmed to body temperature after being injected. The viscosity of the gel can be adjusted through the specifics of the preparation. The gel or other fluid is preferably sufficiently viscid or viscous at body temperature to compress and protect the thecal sac in the manner described above and to remain sufficiently present in the region of interest for at least about 30 minutes. Thus, in some embodiments, the injected gel attains a viscosity that is two, three, six or even ten times that of the fluids that are typically used for epidurograms.

In certain embodiments, the injected medium undergoes a reversible change in viscosity when warmed to body temperature so that it can be injected as a low-viscosity fluid, thicken upon injection into the patient, and be returned to its low-viscosity state by cooling. In these embodiments, the injected medium is injected as desired and thickens upon warming, but can be removed by contacting it with a heat removal device, such as an aspirator that has been provided

with a cooled tip. As a result of localized cooling, the gel reverts to its initial non viscous liquid state and can be easily suctioned up the cooled needle or catheter.

An example of a suitable contrast medium having the desired properties is Omnipaque® 240 available from Nycomed, New York, which is a commercially available non-ionic iodinated myelographic contrast medium. Other suitable injectable media will be known to those skilled in the art. Because of the proximity to the spinal nerves, it is preferred not to use ionic media in the injectable medium. The preferred compositions are reabsorbed relatively rapidly after the procedure. Thus any residual gel compression on the thecal sac after the MILD procedure resolves relatively quickly. For example, in preferred embodiments, the gel would have sufficient viscosity to compress the thecal sac for thirty minutes, and sufficient degradability to be substantially reabsorbed within approximately two hours.

The injected contrast medium further may further include one or more bioactive agents. For example, medications such as those used in epidural steroid injection (e.g. Depo medrol, Celestone Soluspan) may be added to the epidural gel to speed healing and reduce inflammation, scarring and adhesions. The gel preferably releases the steroid medication slowly and prolongs the anti-inflammatory effect, which can be extremely advantageous. Local anesthetic agents may also be added to the gel. This prolongs the duration of action of local anesthetic agents in the epidural space to prolong pain relief during epidural anesthesia. In this embodiment the gel may be formulated to slow the reabsorption of the gel.

The present gels may also be used for epidural steroid injection and perineural blocks for management of acute and chronic spinal pain. Thrombin or other haemostatic agents can be added if desired, so as to reduce the risk of bleeding.

In some embodiments, the gel may also be used as a substitute for a blood patch if a CSF leak occurs. The gel may also be used as an alternative method to treat lumbar puncture complications such as post-lumbar puncture CSF leak or other causes of intracranial hypotension. Similarly, the gel may be used to patch postoperative CSF leaks or dural tears. If the dural sac were inadvertently torn or cut, then gel could immediately serve to seal the site and prevent leakage of the cerebral spinal fluid.

Percutaneous Tissue Excision

After safety zone 40 has been created, the margins of the epidural space are clearly demarcated by the injected medium and can be visualized radiographically if an imagable medium has been used. As mentioned above, percutaneous procedures can now safely be performed on the ligamentum flavum and/or surrounding tissues without injuring the dural sac or nerves and the spinal canal can be decompressed using any of several techniques. Suitable

decompression techniques include removal of tissue from the ligamentum flavum, laminectomy, laminotomy, and ligament retraction and anchoring.

In some embodiments, all or a portion of the ligamentum flavum and/or lamina are excised using a percutaneous tissue excision device or probe 100, which may hereinafter be referred to as the MILD device. As shown schematically in Figure 4, a device 100 may be placed parallel to the posterior and lateral margin of the safety zone 40 with its tip in the ligamentum flavum 26.

Preferred embodiments of the present tissue excision devices and techniques can take several forms. In the discussion below, the distal ends of the tools are described in detail. The construction of the proximal ends of the tools, and the means by which the various components disclosed herein are assembled and actuated, will be known and understood by those skilled in the art.

By way of example, in the embodiment shown in Figure 4 and as illustrated in Figure 5, device 100 may be a coaxial excision system 50 with a sharpened or blunt tip that is placed obliquely into the thickened ligamentum flavum 26 posterior to safety zone 40 under fluoroscopic guidance. The needle is preferably placed parallel to the posterior margin of the canal. Excision system 50 is preferably manufactured from stainless steel, titanium or other suitable durable biocompatible material. As shown in Figures 5-10, an outer needle or cannula 51 has an opening or aperture 52 on one side that is closed during insertion by an inner occluding member 54. Aperture 52 is readily visible under imaging guidance. Once needle 51 is positioned in the ligamentum flavum or other tissue removal site, inner occluding member 54 is removed or retracted so that it no longer closes aperture 52 (Figure 6). Aperture 52 is preferably oriented away from the epidural space so as to further protect the underlying structures from injury during the surgical procedure. If it was not already present in the tool, a tissue-engaging means 56 is inserted through outer needle 51 to aperture 52 so that it contacts adjacent tissue, *e.g.* the ligamentum flavum, via aperture 52.

Tissue-engaging means 56 may be a needle, hook, blade, tooth or the like, and preferably has at least one flexible barb or hook 58 attached to its shaft. The barb 58 or barbs may extend around approximately 120 degrees of the circumference of the shaft. Barbs 58 are preferably directed towards the proximal end of the tool. When needle 56 is retracted slightly, barbs 58 allow it to engage a segment of tissue. Depending on the configuration of barbs 58, the tissue sample engaged by needle 56 may be generally cylindrical or approximately hemispherical. Once needle 56 has engaged the desired tissue, inner occluding means 54, which is preferably provided with a sharpened distal edge, is advanced so that it cuts the engaged tissue section or sample loose from the surrounding tissue. Hence occluding means 54 also functions as a cutting

means in this embodiment. In alternative embodiments, such as Figures 10-14 discussed below, a cylindrical outer cutting element 60 may extended over outer needle 51 and used in place of occluding member 54 to excise the tissue sample.

Referring still to Figures 5-9, once the tissue sample has been cut, tissue-engaging needle 56 can be pulled back through outer needle 51 so that the segment of tissue can be retrieved and removed from the barbs (Figure 8). The process or engaging and resecting tissue may be repeated (Figure 9) until the canal is adequately decompressed.

Referring briefly to Figures 10-14, in other embodiments, a tissue-engaging hook 64 can be used in place of needle 56 and an outer cutting member 60 can be used in place of inner occluding member 54. Hook 64 may comprise a length of wire that has been bent through at least about 270°, more preferably through 315°, and still more preferably through about 405°. Alternatively or in addition, hook 64 may comprise Nitinol™, or any other resilient metal that can withstand repeated elastic deflections. In the embodiment illustrated, hook 64 includes at least one barb 58 at its distal end. In some embodiments, hook 64 is pre-configured in a curvilinear shape and is retained within tool 100 by outer cutting member 60. When cutting member 60 is retracted, the curved shape of hook 64 urges its outer end to extend outward through aperture 52. If desired, hook 64 can be advanced toward the distal end of tool 100, causing it to extend farther into the surrounding tissue. In some embodiments, hook 64 is provided with a camming surface 66. Camming surface 66 bears on the edge of opening 52 as hook 64 is advance or retracted and thereby facilitates retraction and retention of hook 64 as it is retracted into the tool. In these embodiments, hook 64 may not extend through aperture 52 until it has been advanced sufficiently for camming surface 66 to clear the edge of the opening. Hook 64 may alternatively be used in conjunction with an inner occluding member 54 in the manner described above. As above, hook 64 can be used to retrieve the engaged tissue from the distal end of the tool.

In still other embodiments, the tissue-engaging means may comprise a hook or tooth or the like that engages tissue via aperture 52 by being rotated about the tool axis. In such embodiments (not shown) and by way of example only, the tissue-engaging means could comprise a partial cylinder that is received in outer cannula 51 and has a serrated side edge. Such a device can be rotated via a connection with the tool handle or other proximal device. As the serrated edge traverses aperture 52 tissue protruding into the tool via the aperture is engaged by the edge, whereupon it can be resected and retrieved in the manner disclosed herein.

In preferred embodiments, the working tip of tool 100 remains within the ligamentum flavum and does not penetrate the safety zone 40. Nonetheless, safety zone 40 is provided so that even an inadvertent penetration of the tool into the epidural space will not result in damage to the thecal sac. Regardless of the means by which the tissue is engaged and cut, it is preferably

retrieved from the distal end of the tool so that additional tissue segments can be excised without requiring that the working tip of the tool be repositioned. A tissue-removal device such as that described below is preferably used to remove the tissue from the retrieval device between each excision.

Tissue Removal

Each piece of tissue may be removed from barbs 58 by pushing tissue-engaging means 56 through an opening that is large enough to allow passage of the flexible barbs and supporting needle but smaller than the diameter of the excised tissue mass. This pushes the tissue up onto the shaft, where it can be removed with a slicing blade or the like or by sliding the tissue over the proximal end of the needle. Alternatively, needle 56 can be removed and re-inserted into the tool for external, manual tissue removal.

It is expected that in some embodiments, approximately 8-10 cores or segments of tissue will be excised and pushed up the shaft towards the hub during the course of the procedure. Alternatively, a small blade can be used to split the tissue segment and thereby ease removal of the segment from the device. If desired, a blade for this purpose can be placed on the shaft of needle 56 proximal to the barbs.

In an exemplary embodiment, shown in Figures 15-18, the tissue removal device may include a scraper 120 that includes a keyhole slot having a wide end 122 and a narrow end 124. To remove a tissue sample from needle 56 or hook 64, the tissue-engaging device with a mass of excised tissue 110 thereon can be retracted (pulled toward the proximal end of the tool) through wide end 122 of the slot and then re-inserted (pushed toward the distal end of the tool) through narrow end 124 of the slot. Narrow end 124 is large enough to allow passage of the barbed needle, but small enough to remove the tissue mass as the needle passes through. The removed tissue can exit the tool through an opening 113 in the tool body. By shuttling the tissue-engaging device through scraper 120 in this manner, each excised segment of tissue 110 can be removed from the device, readying the device for another excision.

In an alternative embodiment shown in Figure 30, the tissue removal device may be constructed such that tissue is removed from the tissue-engaging device by retracting the tissue-engaging device through narrow end 124 of the slot. As above, narrow end 124 is large enough to allow passage of the shaft of the tissue-engaging device, but small enough to remove the tissue mass as the needle passes through. If the tissue-engaging device is constructed of a tough material, the barbs or the like will cut through the tissue and/or deform and release the tissue. As above, the removed tissue can exit the tool through an opening 113 in the tool body. By shuttling the tissue-engaging device through scraper 120 in this manner, each excised segment of tissue 110 can be removed from the device, readying the device for another excision.

In another alternative embodiment (not shown) an alternative mechanism for removing the tissue segment from needle 56 includes an adjustable aperture in a disc. After the tissue-bearing needle is pulled back through the aperture, the aperture is partially closed. Needle 56 and flexible hooks 58 then can pass through the partially closed aperture but the larger cylinder of tissue cannot. Thus the tissue segment is pushed back onto the shaft. The tissue segment can either be pulled off the proximal end of the shaft or cut off of it. A small blade may be placed just proximal to the barbs to help cut the tissue segment off the shaft. The variable aperture can formed by any suitable construction, including a pair of metal plates with matching edges that each define one half of a central opening. The two pieces may be held apart by springs. The aperture may be closed by pushing the two edges together. In other embodiments, this process can be mechanically automated by using a disc or plate with an opening that is adjustable by a variety of known techniques, including a slit screw assembly or flexible gaskets.

Other cutting and/or grasping devices can be used in place of the system described above. For example, embodiments of the grasping mechanism include but are not limited to: needles with flexible barbs, needles with rigid barbs, corkscrew-shaped needles, and/or retaining wires. The corkscrew-shaped needle shown in Figure 19 works by screwing into the ligamentum flavum in the manner that a corkscrew is inserted in a cork. After the screw engages a segment of tissue, outer cutting element 60 slides over the needle, cutting a segment of tissue in a manner similar to that of the previous embodiment. In some embodiments, the cutting element can be rotated as it cuts.

In other embodiments, shown in Figures 20-22, cannulated scalpel 51 houses a grasping device 70 that includes at least one pair of arcuate, closable arms 72. Closable arms 72 may be constructed in any suitable manner. One technique for creating closable arms is to provide a slotted sleeve 74, as shown. Slotted member 74 preferably comprises an elongate body 75 with at least one slot 76 that extends through its thickness but does not extend to either end of the body. Slot 76 is preferably parallel to the longitudinal axis of the sleeve. On either side of slot 76, a strip 77 is defined, with strips 77 being joined at each end of sleeve 74. It is preferred that the width of each strip 77 be relatively small. In some embodiments, it may be desirable to construct slotted member 74 from a portion of a hollow tube or from a rectangular piece that has been curved around a longitudinal axis. The inner edge of each strip that lies along slot 76 forms an opposing edge 78. The width of the piece is the total of the width of strips 77 and slot 76.

Advancing one end of sleeve 74 toward the other end of sleeve 74 causes each strip 77 to buckle or bend. If strips 77 are prevented from buckling inward or if they are predisposed to bend in the desired direction, they will bend outward, thereby forming arcuate arms 72, which extend through aperture 52 of cannulated scalpel 51, as shown in Figure 21. As they move away

from the axis of body 75, arms 72 move apart in a direction normal to the axis of body 75. Likewise, moving the ends of sleeve 74 apart causes arms 72 to straighten and to move together and inward toward the axis of the device, as shown in Figure 22. As the arms straighten, opposing edges 78 close and a segment of tissue can be capture between them. Tissue within the grasping device may then be resected or anchored via the other mechanisms described herein.

Closable arms 72 may include on their opposing edges 78 ridges, teeth, or other means to facilitate grasping of the tissue. In other embodiments, edges 78 may be sharpened, so as to excise a segment of tissue as they close. In these embodiments, closable arms 72 may also be used in conjunction with a hook, barbed needle, pincers or the like, which can in turn be used to retrieve the excised segment from the device.

Once arms 72 have closed on the tissue, if arms 72 have not cut the tissue themselves, the tissue can be excised using a blade such as cutting element 60 above. The excised tissue can be removed from the inside of needle 51 using a tissue-engaging hook 64 or other suitable means. The process of extending and closing arms 72, excising the tissue, and removing it from the device can be repeated until a desired amount of tissue has been removed.

If desired, this cycle can be repeated without repositioning the device in the tissue. Alternatively, the tool can be rotated or repositioned as desired between excisions. It is possible to rotate or reposition the tool during an excision, but it is expected that this will not generally be preferred. Furthermore, it is expected that the steps of tissue excision and removal can be accomplished without breaching the surface of the ligament, *i.e.* without any part of the device entering the safety zone created by the injected fluid. Nonetheless, should the tool leave the working zone, the safety zone will reduce the risk of injury to the thecal sac.

Ligament Retraction

In some embodiments, the spinal canal may also be enlarged by retracting the ligamentum flavum, either with or without concurrent resection. Retraction is preferably but not necessarily performed after dural compression has been used to provide a safety zone. In addition, the dural compression techniques described above have the effect of pressing the ligamentum flavum back out of the spinal canal and thereby making it easier to apply a restraining means thereto.

Thus, in preferred embodiments, after a safety zone is created by epidural injection of contrast medium or gel, a retraction device 90 as shown in Figure 23 is used to retract and compress the thickened soft tissues around the posterior aspect of the spinal canal, thereby increasing the available space for the dural sac and nerves. In the embodiment shown, retraction device 90 is a double-headed anchor that includes at least one distal retractable tissue-engaging member 91 and at least one proximal tissue-engaging member 92, each of which are supported on a body 94. Retraction device 90 is preferably constructed from an implantable, non-

biodegradable material, such as titanium or stainless steel, but may alternatively be polymeric or any other suitable material. In certain preferred embodiments, body 94 is somewhat flexible. In some instances, flexibility in body 94 may facilitate the desired engagement of barbs 91, 92. Barbs 91, 92 may comprise hooks, arms, teeth, clamps, or any other device capable of selectively engaging adjacent tissue. Barbs 91, 92 may have any configuration that allows them to engage the ligamentum flavum and/or surrounding tissue. Similarly, barbs 91, 92 may be covered, sheathed, pivotable, retractable, or otherwise able to be extended from a first position in which they do not engage adjacent tissue to a second position in which they can engage adjacent tissue.

Figure 23 shows schematically the distal and proximal retractable arms 91, 92 of a preferred ligament anchor 90. The proximal end of the anchor preferably includes a threaded connector 96 or other releasable mechanism that attaches to a support rod 100. Ligament anchor 90 may be attached to a support shaft 112 and sheathed in a guide housing 114. The distal and proximal barbs 91, 92 are prevented by guide housing 114 from engaging surrounding tissue. Housing 102 is preferably a metal or durable plastic guide housing.

The distal end of the device is preferably positioned in the ligamentum flavum under fluoroscopic guidance. If desired, an accessway through the lamina may be provided using an anchored cannula or the like. The device is held in position by support shaft 112. Distal barbs 91 are unsheathed and optionally expanded by pulling back guide housing 102, as shown in Figure 23. Distal barbs 91 are secured in the ligamentum flavum by pulling back on the support shaft 112. With barbs 91 engaging the tissue, the ligamentum flavum is retracted posteriorly by pulling back on support shaft 112. While maintaining traction on the now-retracted ligament, proximal barbs 92 are uncovered and expanded by retracting guide housing 114, as shown in Figure 24. Barbs 92 are preferably positioned in the soft tissues 116 in the para-spinal region so that the device is firmly anchored behind the posterior elements of the spinal canal. Once the proximal end of the anchor is engaged, support shaft 112 may be detached from body 94 as shown in Figure 24. In this manner, the posterior margin 95 of the ligamentum flavum can be held in a retracted position, thereby expanding the canal. The procedure can then be repeated on adjacent portions of the ligamentum flavum until it is sufficiently retracted.

In an alternative embodiment, the proximal end of ligament anchor 90 may be adapted to engage the lamina. This may be accomplished by having the arm posterior to the lamina or by using the laminotomy and suturing the device to the lamina there. A knotted or knotless system or a suture plate can be used.

A second embodiment of the present method uses a plurality of retraction devices 90. In this embodiment, the retraction device is inserted through one lamina in an oblique fashion, paralleling the opposite lamina. After the distal anchor is deployed, the retraction device is pulled

back and across the ligamentum flavum, thereby decompressing the opposite lateral recess of the spinal canal. This is repeated on the opposite side. This same device can also be deployed with a direct approach to the lateral recess with a curved guide housing.

While retraction device 90 is describe above as a double-headed anchor, it will be understood that other devices can be used. For example sutures, barbed sutures, staples or the like can be used to fasten the ligament in a retracted position that reduces stenosis.

Using the percutaneous methods and devices described herein, significant reductions of stenosis can be achieved. For example, a dural sac cross-sectional area less than 100 mm^2 or an anteroposterior (AP) dimension of the canal of less than 10-12 mm in an average male is typically considered relative spinal stenosis. A dural sac cross-sectional area less than 85 mm^2 in an average male is considered severe spinal stenosis. The present devices and techniques are anticipated to cause an increase in canal area of 25 mm^2 per anchor or 50 mm^2 total. With resection and/or retraction of the ligamentum flavum, the cross-sectional area of the dural sac can be increased by 10 mm^2, and in some instances by as much as 20 mm^2 or even 30 mm^2. Likewise, the present invention can result in an increase of the anteroposterior dimension of the canal by 1 to 2 mm and in some instances by as much as 4 or 6 mm. The actual amount by which the cross-sectional area of the thecal sac and/or the anteroposterior dimension of the canal are increased will depend on the size and age of the patient and the degree of stenosis and can be adjusted by the degree of retraction of the ligament.

MILD

The minimally invasive ligament decompression (MILD) devices and techniques described herein allow spinal decompression to be performed percutaneously, avoiding the pain and risk associated with open surgery. Through the provision of a safety zone, the present devices and techniques offer reduced risk of spinal cord damage. In addition to improving nerve function, it is expected that decompression of the spinal canal in the manner described herein will result in improved blood flow to the neural elements by reducing the extrinsic pressure on the spinal vasculature. For these reasons, it is believed that spinal decompression performed according to the present invention will be preferable to decompression operations performed using currently known techniques.

Dural Shield

In some embodiments (not shown), a mechanical device such as a balloon or mechanical shield can also be used to create a protective guard or barrier between the borders of the epidural space and the adjacent structures. In one embodiment a durable expandable device is attached to the outside of the percutaneous laminectomy device, preferably on the side opposite the cutting aperture. The cutting device is inserted into the ligamentum flavum with the expandable device

deflated. With the aperture directed away from the spinal canal, the expandable device is gently expanded via mechanical means or inflated with air or another sterile fluid, such as saline solution, via a lumen that may be within or adjacent to the body of the device. This pushes the adjacent vital structures clear from the cutting aperture of the device and simultaneously presses the cutting aperture into the ligament. As above, the grasping and cutting needles can then be deployed and operated as desired. The balloon does not interfere with tissue excision because it is located on the side opposite the cutting aperture. The cutting needle may be hemispherical (semi-tubular) in shape with either a straight cutting or a sawing/reciprocating blade or may be sized to be placed within the outer housing that separates the balloon from the cutting aperture.

In another embodiment, a self-expanding metal mesh is positioned percutaneously in the epidural space. First the epidural space is accessed in the usual fashion. Then a guide catheter is placed in the epidural space at the site of the intended surgical procedure. The mesh is preferably compressed within a guide catheter. When the outer cover of the guide catheter is retracted, the mesh expands in the epidural space, protecting and displacing the adjacent dural sheath. At the conclusion of the surgical procedure, the mesh is pulled back into the guide sheath and the assembly removed. The mesh is deformable and compresses as it is pulled back into the guide catheter, in a manner similar to a self-expanding mesh stent. There are many commercially available self-expanding stents approved and in use in other applications. However, using a self-expandable mesh as a device within the epidural space to protect and displace the thecal sac is novel.

While preferred embodiments of this invention have been shown and described, modifications thereof can be made by one skilled in the art without departing from the scope or teaching of this invention. For example, the means by which the safety zone is formed may be varied, the shape and configuration of the tissue excision devices may be varied, and the steps used in carrying out the technique may be modified. Accordingly, the invention is not limited to the embodiments described herein, but is only limited by the claims that follow, the scope of which shall include all equivalents of the subject matter of the claims. Likewise, the sequential recitation of steps in a claim, unless explicitly so stated, is not intended to require that the steps be performed in any particular order or that a particular step be completed before commencement of another step.